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Prospective Comparative Study of Anterior Cruciate Ligament Reconstruction Using the Double-Bundle and Single-Bundle Techniques

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Background: The intent of double-bundle anterior cruciate ligament reconstruction is to reproduce the normal anterior cruciate ligament anatomy and improve knee joint rotational stability. However, no consensus has been reached on the advantages of this technique over the single-bundle technique.

Hypothesis: We hypothesized that double-bundle anterior cruciate ligament reconstruction could provide better intraoperative stability and clinical outcome than single-bundle reconstruction.

Type of study: Cohort study; Level of evidence, 2.

Methods: Forty patients with anterior cruciate ligament injury in one knee were recruited; 20 were allocated to a double-bundle anterior cruciate ligament reconstruction group and 20 to a single-bundle anterior cruciate ligament reconstruction group. Intraoperative stabilities at 30° of knee flexion were compared between the 2 groups using a navigation system. Clinical outcomes including Lysholm knee scores, Tegner activity scores, Lachman and pivot-shift test results, and radiographic stabilities were also compared between the 2 groups after a minimum of 2 years of follow-up.

Results: Intraoperative anterior and rotational stabilities after anterior cruciate ligament reconstruction in the double-bundle group were significantly better than those in single-bundle group (P = .020 and P < .001, respectively). Nineteen patients (95%) in each group were available at a minimum 2-year follow-up. Clinical outcomes including Lysholm knee and Tegner activity scores were similar in the 2 groups at 2-year follow-up (P > .05). Furthermore, stability results of the Lachman and pivot-shift tests, and radiologic findings at 2-year follow-up failed to reveal any significant intergroup differences (P > .05).

Conclusion: Although double-bundle anterior cruciate ligament reconstruction produces better intraoperative stabilities than single-bundle anterior cruciate ligament reconstruction, the 2 modalities were found to be similar in terms of clinical outcomes and postoperative stabilities after a minimum of 2 years of follow-up.

Keywords: anterior cruciate ligament; double-bundle; single-bundle; intraoperative stabilities; clinical outcomes

In vitro biomechanical studies have demonstrated that the anteromedial and posterolateral bundles of the anterior cruciate ligament (ACL) synergistically stabilize the knee joint in response to anterior tibial loads and combined rotational loads.[7,21,33] Some biomechanical studies have concluded that double-bundle ACL reconstruction restores anterior and rotational stabilities in ACL-deficient knees more closely to the intact knee than single-bundle ACL reconstruction.[16,28,33] In particular, additional posterolateral bundle reconstruction has been reported to increase rotational stability significantly compared with single-bundle ACL reconstruction.[11,20] These findings have encouraged several authors to propose innovative surgical techniques for reconstructing the 2 bundles of the ACL

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and they have reported favorable clinical outcomes in literature.[§]

However, there are clinical and biomechanical studies that have concluded that double-bundle ACL reconstruction has no significant advantage over single-bundle ACL reconstruction.[1-3,8,22,25] A literature review indicated that although double-bundle ACL reconstruction is capable of reproducing the 2 functional bundles of the ACL at their anatomical insertion sites, no consensus has been reached on the advantage of this technique over the single-bundle technique. Furthermore, few studies have quantitatively and comparatively evaluated the rotational stability after single-bundle and double-bundle ACL reconstructions.[11] No comparative study has been conducted on the intraoperative stability and clinical outcome obtained using these 2 modalities.

In this study, we hypothesized that double-bundle ACL reconstruction provides better intraoperative stability and clinical outcome than single-bundle reconstruction. The objective was to perform a prospective study to compare the intraoperative stabilities and short-term clinical outcomes of a single-bundle ACL reconstruction with those of a double-bundle ACL reconstruction.

MATERIALS AND METHODS

Forty consecutive patients awaiting ACL reconstruction were recruited in this prospective study. Only those patients who received unilateral primary ACL reconstruction without combined ligamentous surgery were included. Patients with objectively detectable lateral, medial, or posterior instability, who were thus suspected of having multiple ligament injuries, were excluded. We also excluded patients who had undergone previous open or arthroscopic surgeries and those with radiologic degenerative changes of more than grade III in either knee. This study was approved by the institutional review board of Chonnam National University Hwasun Hospital, and written informed consent was obtained from all patients.

The 40 patients were equally allocated, in an alternative fashion by the order of treatment, to the single-bundle and double-bundle groups. The average time from injury to reconstruction in the double-bundle group was 8.3 months (range, 1-26). This group contained 16 men and 4 women with an average age of 35.5 years at surgery (range, 19-58 years). The average time from injury to reconstruction in the single-bundle group was 7.6 months (range, 2-20). This group contained 15 men and 5 women with an average age at surgery of 30.3 years (range, 17-50).

In terms of combined meniscal injury, there were 7 medial meniscal injuries in the double-bundle group; 4 were repaired using the inside-out technique and the remaining 3 were treated by partial meniscectomy. In addition, there were 3 lateral meniscal injuries, all of which were treated by partial meniscectomy. There were 6 medial meniscal injuries in the single-bundle group; 3 were repaired using the inside-out technique and the remaining 3 were treated by partial meniscectomy. The 2 lateral meniscal injuries in the single-bundle group were treated by partial meniscectomy. Time from injury to surgery, age at surgery, gender, follow-up periods, and rate of meniscectomy were not significantly different between the 2 groups ($P > .05$).

Surgical Techniques and Intraoperative Stability Testing

Both the single-bundle and double-bundle arthroscopic ACL reconstructions were performed by the same surgeon (E.K.S.), who had experience with more than 100 cases of single-bundle reconstruction and 20 cases of double-bundle reconstruction before this study was initiated. An EndoButton CL (Smith & Nephew, Andover, Massachusetts) was used for femoral side fixation and a bioabsorbable interference screw (Linvatec, Largo, Florida) and staples were used for tibial side fixation in both groups. After routine diagnostic arthroscopy, meniscal repair or meniscectomy was performed when concomitant meniscal injuries were present.

For double-bundle ACL reconstruction, tibialis anterior allografts were prepared to make 2 double-looped grafts of 5- to 6-mm diameter for the posterolateral bundle (PLB) and of 7-mm diameter for the anteromedial bundle (AMB). Both graft loop ends were connected to an EndoButton loop and the free ends were prepared with whipstitch sutures. The PLB tibial tunnels were placed at the center of the PLB footprint on the tibia (5 mm anterior to the posterior cruciate ligament) using a tibial drill guide set at an angle of 45° to the horizontal plane with a starting point just anterior to the superficial medial collateral ligament. On the other hand, AMB tunnels were positioned in a more anteromedial position on the tibial footprint (7 mm anterior and 5 mm medial from PLB tunnels) using a tibial drill guide set at an angle of 55° to the horizontal plane.

Femoral AMB tunnels were prepared through anteromedial portals at the 1:00-o'clock position for the left knee or at the 11:00-o'clock position for the right knee. Femoral PLB tunnel locations were prepared through the accessory anteromedial portal at 5 to 8 mm from the anterior lateral femoral condyle cartilage, and 3 to 5 mm from the inferior lateral femoral condyle cartilage with the knee in 90° of flexion. To establish femoral fixation, grafts for the PLB and AMB were passed through each bony tunnel and an EndoButton was flipped over the lateral femoral cortex. Knees were then cycled approximately 10 times through a full range of motion. The PLB and AMB grafts were fixed at 10° to 20° of flexion and at 60° to 70° of flexion, respectively, using bioabsorbable interference screws under 40 N of tension. Additional fixation on the tibial side was performed using a single staple (Figure 1A).

For single-bundle ACL reconstructions, the tibialis anterior allograft was also prepared as a double-looped graft (diameter, 8-9 mm). After tibial tunnel preparation using a drill guide within the center of the ACL insertion, a femoral tunnel was created through the tibial tunnel at

[§]References 1, 4, 9, 10, 13, 16, 17, 19, 23, 29, 30.

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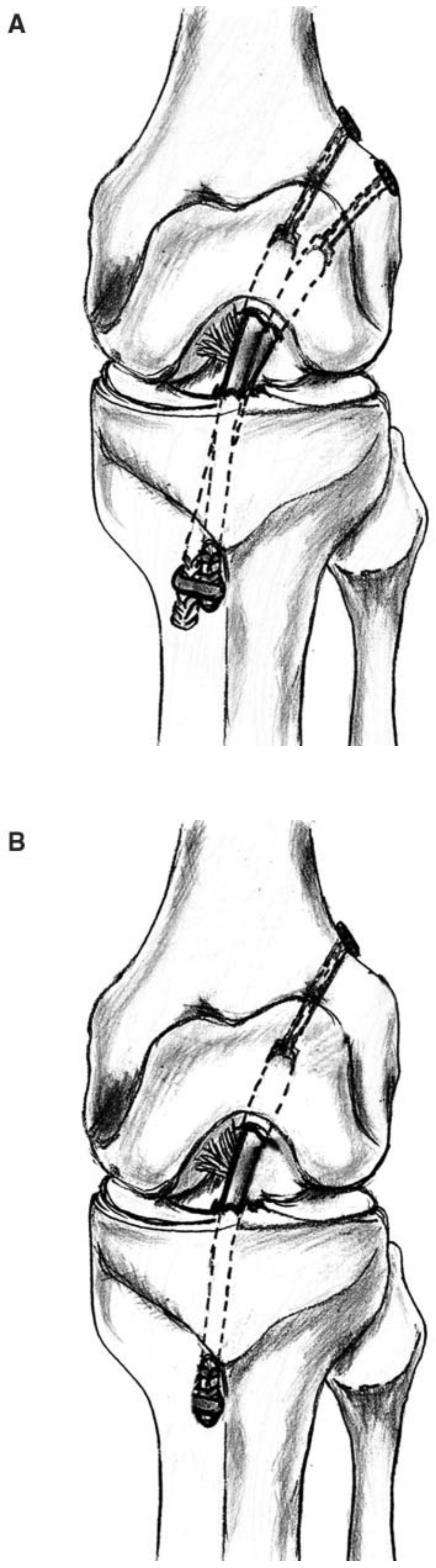

Figure 1. Schematic drawings of (A) double-bundle anterior cruciate ligament reconstruction, and (B) single-bundle anterior cruciate ligament reconstruction.

Figure 2. Navigation setup and anterior stability test after anterior cruciate ligament reconstruction.

1:30-o'clock for left knees or at 10:30-o'clock for right knees. The fixation materials used were as previously described for double-bundle reconstruction. Knees were then cycled approximately 10 times through a full range of motion, and the graft on the tibial side was fixed at 10° to 20° of flexion, also under 40 N of tension (Figure 1B).

A computer navigation system (OrthoPilot, B. Braun-Aesculap, Tuttlingen, Germany) was used for intraoperative stability measurement. Femoral and tibial transmitters were firmly secured to the femur and tibia using a fixation instrument with 2 K-wires. After extra-articular anatomical landmarks were registered, including the tibial tuberosity, the anterior tibial crest, and the medial and lateral tibial plateaus, knee kinematics between 0° and 90° of flexion were registered. Knee stability testing at 30° of knee flexion was performed by a single surgeon (E.K.S.) (this was chosen to better simulate the clinical situation; eg, the Lachman test) with maximal manual force. We applied the anterior tibial load to determine tibial anterior translation and the internal-external rotational tibial load to determine total rotation (internal plus external rotation) before ACL reconstruction and after complete graft fixation in both groups (Figure 2). To minimize bias, the surgeon was not informed of the stability data.

Clinical Outcomes and Radiologic Stability Assessments

Patients were evaluated preoperatively and at 1 and 2 years postoperatively. Two patients had relocated and could not be reached for 2-year follow-up (1 in each group). Thus, 19 patients (95%) in each group were available at a minimum of 2 years of follow-up (range, 24-31 months). Clinical results were evaluated using range of motion, Lysholm knee scores,[15] Tegner activity scores,[26] and the Lachman and pivot-shift tests. Radiologic stability was evaluated by performing an instrumented laxity test using a Telos device (Telos stress device, Austin & Associates, Fallston, Maryland) at 30° of knee flexion and with a 20-lb anterior tibial load applied to the proximal tibia. The

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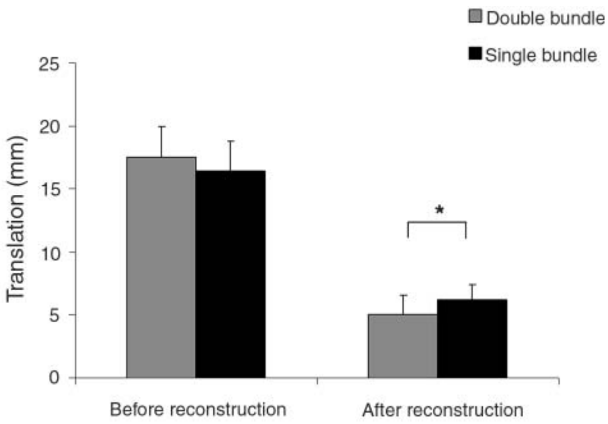

Figure 3. Comparisons of intraoperative anteroposterior translations at 30° of flexion. *Indicates statistical significance between the 2 groups ($P < .05$). Error bars represent SD.

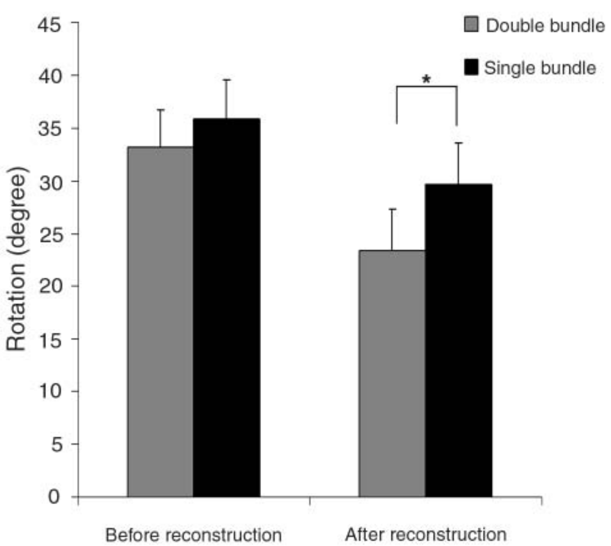

Figure 4. Comparisons of intraoperative rotational stabilities at 30° of flexion. *Indicates statistical significance between the 2 groups ($P < .05$). Error bars represent SD.

normal, contralateral side was used as a control. Differences in anterior translations of the reconstructed knee and its normal contralateral side were used to evaluate the restoration of normal laxity of the knee after ACL reconstruction using single-bundle or double-bundle technique.

Statistical Analysis

The sample size of each group was determined beforehand by using statistical power analysis. The power analysis indicated that to detect a difference of 1.7 mm with a variance of 1.7 mm in anteroposterior stability between the 2 groups,[30] 16 patients were required per group (power = 0.8 and $P < .05$). Therefore, we included 20 patients per group to cope with possible losses.

Nonparametric tests were used for intergroup comparisons. The Mann-Whitney test was used to analyze continuous data, and Fisher's exact test was used to analyze categorical data. The level of significance was set to .05. Analysis was performed using SPSS software (SPSS for Windows Release 10.0, SPSS Science Inc., Chicago, Illinois).

TABLE 1
Comparison of the 2 Groups With Respect to Clinical Outcomes at 1- and 2-Year Follow-ups

Outcome	Double-Bundle Group	Single-Bundle Group	*P* Value
Lysholm knee score			
Preoperative (n = 20/20)	63.6 ± 9.1	61.4 ± 12.3	.789
Postoperative			
1 year (n = 20/20)	94.0 ± 5.9	92.0 ± 6.8	.296
2 years (n = 19/19)	93.3 ± 6.2	92.5 ± 7.7	.953
Tegner activity score			
Preinjury (n = 20/20)	7.1 ± 1.4	6.9 ± 1.4	.595
Postoperative			
1 year (n = 20/20)	6.8 ± 1.3	6.7 ± 1.8	.989
2 years (n = 19/19)	6.9 ± 1.1	6.9 ± 1.3	.904
Side-to-side difference			
Preoperative (n = 20/20)	10.0 ± 2.0	9.3 ± 2.3	.263
Postoperative			
1 year (n = 20/20)	2.4 ± 2.1	2.7 ± 2.3	.822
2 years (n = 19/19)	2.7 ± 1.9	2.8 ± 2.0	.872
Extension limitation			
Postoperative			
1 year (n = 20/20)	0.9 ± 2.0	0.8 ± 1.8	.674
2 years (n = 19/19)	0.8 ± 1.9	0.5 ± 1.6	.636

RESULTS

The average operative time was 56.0 minutes (range, 45-74) in the single-bundle group and 71.6 minutes (range, 50-115) in the double-bundle group ($P = .001$). No postoperative complications such as iatrogenic cartilage injury, serious tunnel malposition, graft fixation failure, infection, fracture, or deep vein thrombosis were observed in either group during surgery.

Intraoperative Stabilities

The average anterior translations were significantly improved in both groups after ACL reconstruction, that is, from 16.6 ± 2.4 mm to 6.1 ± 1.2 mm in the single-bundle group and from 17.5 ± 2.5 mm to 5.1 ± 1.5 mm in the double-bundle group (Figure 3). There was a significant intergroup difference ($P = .020$). Average tibial rotations showed a significant improvement after ACL reconstruction: the tibial rotation was improved from 35.1° ± 3.1° to 29.5° ± 3.8° in the single-bundle group and from 33.2° ± 3.6° to 23.3° ± 4.0° in the double-bundle group (Figure 4). There was a significant intergroup difference ($P < .001$).

Clinical Outcomes and Radiologic Stabilities

Preoperative average Lysholm knee scores were 61.4 (range, 37-80) in the single-bundle group and 63.6 (range, 42-80) in the double-bundle group ($P = .79$). These scores

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TABLE 2
Comparison of the 2 Groups With Respect to Knee Stability According to Lachman Test at 1- and 2-Year Follow-ups[a]

	Double-Bundle Group			Single-Bundle Group		
Grade	Preop (n = 20)	Postop 1 Year (n = 20)	Postop 2 Years (n = 19)	Preop (n = 20)	Postop 1 Year (n = 20)	Postop 2 Years (n = 19)
0	0	15	14	0	14	12
1+	0	4	4	0	4	5
2+	5	1	1	4	2	2
3+	15	0	0	16	0	0

[a]Preop, preoperative; Postop, postoperative.

TABLE 3
Comparison of the 2 Groups With Respect to Knee Stability as Determined by the Pivot-Shift Test at 1- and 2-Year Follow-ups[a]

	Double-Bundle Group			Single-Bundle Group		
Grade	Preop (n = 20)	Postop 1 Year (n = 20)	Postop 2 Years (n = 19)	Preop (n = 20)	Postop 1 Year (n = 20)	Postop 2 Years (n = 19)
0	0	17	14	0	13	11
1+	2	3	4	1	5	6
2+	5	0	1	4	2	2
3+	13	0	0	15	0	0

[a]Preop, preoperative; Postop, postoperative.

were significantly improved in both groups at 1- and 2-year follow-ups without significant intergroup differences (Table 1). Average activity levels according to the Tegner scoring system after the surgery were restored to preinjury levels in both groups. However, there were no significant differences between 2 groups at 1- and 2-year follow-ups ($P > .05$; Table 1).

Lachman test results are shown in Table 2. At 2-year follow-up, 2 patients showed grade II laxity in the single-bundle group and 1 patient in the double-bundle group ($P = 1.00$). Furthermore, the pivot-shift test at 1- and 2-year follow-ups failed to reveal any intergroup difference (Table 3).

The limitation of the extension in the knee was 0.8° ± 1.9° in the double-bundle group and 0.5° ± 1.6° in the single-bundle group ($P = .64$) at 2-year follow-up (Table 1). In addition, no problematic loss of flexion or extension (>10°) was observed in either group at 1- and 2-year follow-ups.

In the single-bundle group, the average side-to-side difference in the knee according to the radiologic stability before reconstruction was 9.3 ± 2.3 mm (range, 6-14) and this improved to 2.8 ± 2.0 mm (range, 0-9) at 2-year follow-up ($P < .01$). Similarly, in the double-bundle group, average side-to-side difference was 10.0 ± 2.0 mm (range, 7-14) before reconstruction and this improved to 2.7 ± 1.9 mm (range, 0-7) at 2-year follow-up ($P < .01$). However, no significant differences were evident between the 2 groups at 1- and 2-year follow-ups with respect to side-to-side differences (Table 1).

DISCUSSION

This study compared the single-bundle and double-bundle ACL reconstructions in terms of intraoperative stabilities and clinical outcomes with a minimum of 2 years of follow-up. Our data demonstrated that the double-bundle ACL reconstruction showed better anterior and rotational intraoperative stabilities than the single-bundle ACL reconstruction. However, after a minimum of 2 years of follow-up, knee stabilities according to Lachman scores, pivot-shift tests, and stress radiographs were similar between the 2 ACL reconstruction groups. Furthermore, we were unable to identify any differences between the 2 techniques in terms of functional outcomes based on Lysholm knee and Tegner activity scores at 2-year follow-up. Therefore, our hypothesis was not positively proved by the data obtained in this study.

Several biomechanical studies have reported that double-bundle ACL reconstruction is more effective in restoring anterior and rotational stabilities in ACL-deficient knees than single-bundle ACL reconstruction.[16,28,33] For instance, in an in vitro study, Yagi et al[28] concluded that under a 134-N anterior tibial load, anterior tibial translation was found to be significantly improved after double-bundle ACL reconstruction but not after single-bundle ACL reconstruction. In the present study, objective in vivo data on anteroposterior stability were obtained using a navigation system during ACL reconstruction and confirmed the superiority of double-bundle ACL reconstruction observed by other authors[19,28,30] at the time zero point after ACL reconstruction.

Rotational control of the tibia during double-bundle ACL reconstruction remains a debatable issue. Woo et al[27] found that single-bundle ACL reconstruction techniques that were mainly designed to resist anterior tibial loading, insufficiently control combined rotatory loads. Yoo et al[31] found that ACL reconstruction overly constrained the tibial rotation under simulated muscle loads. These studies indicate that the complex role of an intact ACL cannot be restored by conventional single-bundle ACL reconstruction.[14] Yagi et al[28] also concluded that anatomical double-bundle ACL reconstruction effectively controls internal tibial rotation more than single-bundle ACL reconstruction. Gabriel et al[6] and Zantop et al[33] demonstrated in cadaveric studies the importance of the posterolateral bundle as a stabilizer against internal rotatory loads. The present study demonstrates that double-bundle ACL reconstruction is significantly superior to single-bundle ACL reconstruction in terms of intraoperative rotational stability, which implies that double-bundle ACL reconstruction effectively reduces residual pivot-shift phenomenon after ACL reconstruction.

In a navigation system-based cadaveric study, Steckel et al[24] found that double-bundle ACL reconstruction showed a trend toward the overcorrection of rotational laxities as compared with intact ACL. However, in the present study we did not observe this type of overcorrection, and our finding of an average of 23.3° rotational laxity in double-bundle ACL reconstruction was similar to the intact knee level of Steckel et al.[24] A direct comparison with their

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study is difficult because of subject variation, reconstruction methods, and different loading conditions.

Even though several prospective comparative clinical studies have been conducted on single-bundle versus double-bundle ACL reconstruction, inconsistent conclusions about the superiority of one technique over the other in clinical results were reported. Muneta et al[19] and Siebold et al[23] found no significant differences between the single-bundle and double-bundle ACL reconstructions in clinical functional results, although the double-bundle technique showed better stability results according to KT-1000 arthrometer measurements, the Lachman test, and the pivot-shift test. On the other hand, Asagumo et al[3] concluded that the double-bundle technique offers no advantage over the single-bundle technique in terms of stability or clinical outcome, although extension deficit was more frequently observed in the double-bundle group. In the present study, despite superior intraoperative stability results, the double-bundle technique failed to produce advantages in clinical outcomes and stabilities at 1- and 2-year follow-ups. Furthermore, in the present study neither group showed significant loss of extension (>10°) after a minimum of 2 years of follow-up. This may have been because the clinical scoring systems and stability tests that were used in our study—Lysholm and Tegner scores, the Lachman test, the pivot-shift test, and side-to-side differences determined using stress radiographs—might not be sensitive enough to detect 2 mm or 3° stability differences between single-bundle and double-bundle ACL reconstructions. More objective measurements of clinical function and stability are needed in the future to quantify differences between the 2 techniques in the clinical setting. Differences between the findings of this study and those of other studies may also be because of the different surgical techniques used, such as tunnel positions, graft types, graft fixation techniques, and fixation angles.

In the present study, as has been previously reported,[12,23] approximately 15 minutes of additional operating time was needed for double-bundle ACL reconstruction. However, no complications possibly related to this increased operating time, such as infection or thrombotic events, were encountered. Furthermore, in the present study no complications related to surgical techniques such as iatrogenic cartilage injury, serious tunnel malposition, graft fixation failure, or fractures were observed in either study group. This result suggests that the complication rates of the 2 techniques are minimal when surgery is performed by an experienced surgeon.

There are certain limitations of the present study that should be noted. First, the loads used for intraoperative stability testing were applied manually, and tests were performed by a single surgeon. However, several in vivo studies[5,11,18,32] have shown high intrasurgeon and intersurgeon reliabilities for stability measurement using navigation systems with manual loads. Thus, we considered our stability data reliable and suitable for this comparative study. Second, when designing this study, we calculated the number of subjects using the stability data obtained using a KT-1000 arthrometer. However, surgeons tend to have different opinions regarding outcome measures for determining the superiority of a technique, and thus the sample size and outcome measures chosen are debatable. Finally, we used a standard position for the femoral tunnel instead of a more horizontal position in the single-bundle group, and an allograft rather than an autograft in both study groups. Additional studies involving a more horizontal femoral tunnel position in single-bundle or autograft reconstruction are necessary.

In conclusion, despite better intraoperative stabilities after reconstruction, the double-bundle ACL reconstruction technique failed to demonstrate any advantage over single-bundle ACL reconstruction with regard to clinical outcomes and stabilities after a minimum follow-up of 2 years. To establish the clinical utility of double-bundle ACL reconstruction for ACL-deficient knees, further clinical studies are necessary to examine objectively its effects on rotatory stability and long-term graft function.

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